AMENDMENTS TO THE CLAIMS

The following listing of claims replaces all prior listings and version of claims in this application.

1. (Currently Amended) A process for purifying alpha-1 proteinase inhibitor (API) from an unpurified mixture of proteins comprising:

(a) dispersing the unpurified mixture of proteins containing API in an aqueous medium;

(b) removing a portion of contaminating lipids and proteins by adding a lipid removal agent to the aqueous dispersion and precipitating the portion of contaminating proteins from said aqueous dispersion;

(c) loading an API-containing supernatant of step (b) containing API on a first anion exchange resin with a buffer solution having pH and conductivity such that API is retained on the first anion exchange resin;

(d) eluting an API-containing fraction from said first anion exchange resin with a same type of buffer as in step (c) having adjusted pH and conductivity;

(e) loading an API-containing fraction of step (d) on a cation exchange resin in said same type of buffer having appropriate pH and conductivity such that API is not retained on the cation exchange resin;

(f) collecting a flow-through of step (e) that contains API;

(g) loading an API-containing fraction of step (f) on a second anion exchange resin with said same type of buffer having appropriate pH and conductivity such that API binds to the second anion exchange resin; and

(h) eluting API from said second anion exchange resin with said same type of buffer having adjusted pH and conductivity to obtain a stable solution containing purified, active API.

2. (Original) The process of claim 1, wherein the API obtained comprises at least 90% active API out of the total API recovered.

3. (Original) The process of claim 2, wherein the API obtained comprises at least 95% active API out the total API recovered.

4. (Original) The process of claim 1, wherein the API solution comprises at least 90% API out of the total protein recovered.

5. (Original) The process of claim 4, wherein the API obtained comprises at least 95% API out of the total protein recovered.

6. (Original) The process of claim 1, wherein the buffer solution is other than citrate based buffer.

7. (Original) The process of claim 1, wherein the buffer solution is acetate-based buffer.

8. (Original) The process of claim 1 further comprising a viral inactivation step.

9. (Original) The process of claim 8 wherein the viral inactivation step comprises adding a solvent and a detergent to the API of step (f) collected from the cation exchange resin.

10. (Original) The process of claim 9 wherein the detergent is a non-ionic detergent.

11. (Original) The process of claim 1, further comprising a viral removal step.

12. (Original) The process of claim 11, wherein the viral removing step comprises nanofiltration.

13. (Original) The process of claim 1, wherein the unpurified mixture of proteins is selected from the group consisting of Cohn Fractions, human blood plasma and plasma fractions.

14. (Original) The process of claim 13 wherein the unpurified mixture of proteins is Cohn fraction IV-paste.

15. (Original) The process of claim 1 wherein the lipid removing agent is silicon dioxide.

16. (Original) The process of claim 1 wherein the portion of contaminating lipids and proteins is precipitated by polyalkylene glycol.

17. (Original) The process of claim 16, wherein the polyalkylene glycol is polyethylene glycol.

18. (Original) The process of claim 16 wherein precipitation is performed at a pH from about 5.0 to about 6.5.

19. (Original) The process of claim 1, wherein the first and the second anion exchange resin is a DEAE-Sepharose resin.

20. (Original) The process of claim 1 wherein the cation exchange resin is Carboxymethyl-Sepharose resin.

21. (Original) The process of claim 1, wherein the pH of the buffer solution is at a pH of between 5.5 and 6.5 for the elution of the API from the first and the second anion exchange resin.

22. (Original) The process of claim 1, further comprising changing the ionic composition of the solution containing purified, active API to contain a physiologically compatible ion and sterilizing the resulted solution.

23. (Original) The process of claim 22, wherein the solution containing API is concentrated before the ion exchange.

24. (Original) The process of claim 22, wherein the physiologically compatible ion is selected from the group consisting of a phosphate ion, a chloride ion and combinations thereof.

Claims 25. to 39. (Canceled)

40. (New) The process of claim 1 which provides a purified active API which is stable without the addition of a protein stabilizer.

41. (New) The process of claim 40 which further comprises formulating a pharmaceutical preparation comprising the purified active stable API as an active ingredient.

42. (New) The process of claim 41 wherein the pharmaceutical preparation is formulated with the solution of purified, active stable API and is sterilized.

43. (New) The process of claim 42 wherein the preparation is formulated to have a pH in the range of 6.5-7.5.

44. (New) The process of claim 42 wherein the preparation is formulated to have a protein concentration between about 1% to about 3%.

45. (New) The process of claim 42 wherein the preparation is formulated to be devoid of any protein stabilizer.

46. (New) The process of claim 45 wherein the preparation is formulated to have the API stable for at least 3 months when the pharmaceutical preparation is stored at a temperature of between 20°C to 25 °C.

47. (New) The process of claim 45 wherein the preparation is formulated to have the API stable for at least 12 to 36 months when the pharmaceutical composition is stored at a temperature of between 2°C to 8 °C.

48. (New) The process of claim 41 wherein the preparation is formulated to also have an excipient, diluent or a carrier.

49. (New) The process of claim 41 wherein the preparation is formulated to be administered intravenously.

50. (New) The process of claim 41 wherein the preparation is formulated to be administered by inhalation.

51. (New) The process of claim 41 which further comprises treating a subject in need thereof by administering the pharmaceutical preparation so that the subject receives a therapeutically effective amount of API.

52. (New) The process of claim 51, wherein the subject is treated for a disease or disorder selected from the group consisting of pulmonary emphysema, chronic obstructive pulmonary disorder, cystic fibrosis associated lung diseases and disorders, psoriasis and atopic dermatitis.

53. (New) The process of claim 51, wherein the subject is treated for pulmonary emphysema.

54. (New) The process of claim 51, wherein the subject is treated for cystic fibrosis associated lung disease or disorder.